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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,135	04/06/2007	David Spriggs	MSK.P-071	3258

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
06/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,135	SPRIGGS ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Spriggs et al.

1. Claims 1-14 are pending. Claims 15 and 16 have been cancelled.

2. Claims 1-14 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed on 5/11/2007 has been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 9 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/19206 (Pub. Date: 4/6/2000, IDS).

WO 00/19206 teaches a method for screening a cancer, detecting a cancer and/or evaluating the prognosis of a cancer in a mammal, said method comprising (a) obtaining a biological sample from said mammal; (b) measuring a level of YKL-40 in said sample and comparing the level to the YKL-40 level found in that of a normal healthy mammal or normal population wherein a statistically significant difference in YKL-40 levels indicates the presence of cancer (see abstract, page 2, lines 30-33, page

13, lines 1-2, claims 47 and 51). WO 00/19206 teaches that the biological sample is plasma or serum (see claim 49), and the level of YKL-40 is measured using an immunoassay (see claim 57). WO 00/19206 discloses that elevated levels of YKL-40 are indicative of the presence of a cancer in undiagnosed subjects and indicate likely recurrences of the cancer in subjects diagnosed as having a cancer (see abstract). WO 00/19206 discloses that serum YKL-40 can identify patients with cancer before clinical symptoms appear, and therefore before the cancer would normally be discovered (see page to, lines 4-5). WO 00/19206 discloses that the median concentration of YKL-40 detected from control healthy group is 80 µg/L in children (aged 6-17 years) and 102 µg/L in adults (aged 20-79 years) (see page 12, paragraph 4, lines 3-5). WO 00/19206 teaches that the statistically significant elevated (relative to a normal healthy human) serum YKL-40 level is greater than the 95% of controls, which is about 207 µg/L for subjects age 20-69 ("prognostically significant levels") (see page 28, 4th paragraph, lines 5-12). WO 00/19206 discloses that serum YKL-40 concentration in 120 healthy women (aged 18-69 years) were established for use as control values, and the median serum YKL-40 concentration was 99 µg/L (see page 46, lines 12-14). WO 00/19206 discloses that two patients having YKL-40 concentration of 196 µg/L and 298 µg/L, respectively, developed ovarian caner within 5 years after YKL-40 determination (see page 59, Table 6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/19206 (Pub. Date: 4/6/2000, IDS), in view of Marton et al. (US 2003/0175832A1, Pub. Date 9/18/2003, effective filing date 11/16/2001), and Xu et al. (US 5,486,456, Date of Patent 1/23/1996).

The teachings of WO 00/19206 have been set forth above as they apply to claims 1, 2, 9 and 11-14 (see paragraph 5).

While WO 00/19206 teaches comparing the level of YKL-40 in a test subject to a median level of YKL-40 in normal populations wherein a level greater than 95% of the median level of healthy controls is considered statistically significant, WO 00/19206 does not teach comparing the level of YKL-40 in a test subject to a mean level of YKL-40 detected in normal populations. WO 00/19206 does not teach that the pre-determined threshold is at least two standard deviations higher than the mean amount of YKL-40 detected in a population of individuals who do not have ovarian cancer. WO 00/19206 does not teach detection of CA-125. However these deficiencies are made up for in the teachings of Marton and Xu et al.

Marton et al. disclose that for the purpose of monitoring disease development or progression, or monitoring an individual at (high) risk, generally the level of HLA-DR

expression by CD14+ cells and/or the percentage of CD16+/CD14+ cells and/or the number of CD14+/CD16+ cells in a sample may be compared with the mean or median level in samples taken from healthy individuals or from non-ALS patients, matched where necessary for sex and/or age. Alternatively, results of these indicia can be compared with the values or the mean or median values of results from samples taken from the same monitored individual at various time points (see paragraph [0077]).

Xu et al. disclose that the CA125 is the current serum marker of choice for monitoring ovarian cancer (see column 1, lines 36-37). Xu et al. teach a method of diagnosis of ovarian cancer by detection two markers including CA125 (see claims 1 and 6). Xu et al. disclose the use of the mean value plus two standard deviations of healthy controls as the cutoff value in diagnosis of ovarian cancer (see column 15, lines 25-28).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of WO 00/19206 to compare the level of YKL-40 detected in a test subject to a mean level of YKL-40 detected in normal populations, and use the mean plus two standard deviations of normal populations as the cutoff values for diagnosis of ovarian cancer in view of Marton and Xu. One of ordinary skill in the art would have been motivated to do so because mean plus two standard deviations of healthy controls was wildly used in the prior art as cutoff value for determination of statistic significance of test results as shown by the teachings of Marton and Xu. Marton et al. disclose that the test results can be compared with either mean or median level in samples taken from healthy individuals. Xu teach that mean

plus two standard deviations of healthy controls can be used as cutoff value for identifying positive subjects. It is obvious to combine prior art elements according to known methods to yield predictable results. One of ordinary skill in the art would have a reasonable expectation of success to modify the method of WO 00/19206 to compare the level of YKL-40 detected in a test subject to a mean level of YKL-40 detected in normal populations, and use the mean plus two standard deviations of normal populations as cutoff values for diagnosis of ovarian cancer because method of calculating mean and standard deviations were well known in the prior art.

In addition, Marton et al. teach using age and sex matched individuals as normal controls. For diagnosis of ovarian cancer in subjects at ages 50-60, one would have been motivated to include healthy individuals at ages 50-60 in the control group in view of Marton et al. These individuals have increased risk factors for ovarian cancer given the fact that age and menopause are known risk factors for ovarian cancer.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one of ordinary skill in the art would have been motivated to further detect CA125 in view of Xu for the purpose of improving diagnosis accuracy. One of ordinary skill in the art would have a reasonable expectation of success to detect CA125 because CA125 was a widely used serum marker for detecting ovarian cancer.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643